

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Reply, Application of: **Couto et al.**

Serial No.: **10/635,117**

Group No.: **1644**

Filed: **08/06/03**

Examiner: **Mondesi, R.**

For: **METHODS OF TANGENTIAL FLOW FILTRATION AND AN APPARATUS THEREFORE**

Attorney Docket Number: **GTC-207**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT AFTER THE FIRST OFFICE ACTION ON THE MERITS BUT BEFORE MAILING OF EITHER A FINAL ACTION OR A NOTICE OF ALLOWANCE (37 CFR 1.97(c))**

Dear Sir,

**1. Authority**

Pursuant to 37 CFR § § 1.56 and 1.97-1.99, the Applicant cites to the Examiner documents containing information which, in good-faith judgment of the Applicant, may be relevant to the subject matter claimed in the above-identified application. The Applicant also encloses copies of the English-language cited documents.

In submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, or the extent of any search performed, or that more relevant information does not exist.

In submitting this Information Disclosure Statement, the Applicant makes no representation that any document cited in this Information Disclosure Statement is, or is considered to be prior art as defined by 35 USC § § 102 and 103.

**2. Time of transmittal of accompanying Information Disclosure Statement**

The Information Disclosure Statement transmitted herewith is being filed *after* three months of the filing date of this application *and after* the mailing date of the first Office action on the merits, but *before* the mailing date of either:

09/20/2004 KBETEM1 00000028 502092 10635117

(1) a final action under § 1.113, or

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(2) a notice of allowance under § 1.311, whichever occurs first.

**CERTIFICATE OF MAILING BY EXPRESS MAIL**

I hereby certify that under 37 CFR §1.10 that this correspondence is being deposited on September 17, 2004 with the United States Postal Service as Express Mail Post Office to Addressee with sufficient postage in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

  
Kristin Kaberry

Applicant elects to pay the fee set forth in 37 CFR 1.17(p) for submission of an Information Disclosure Statement under § 1.97(c). Please charge the fee of \$180.00 to Deposit Account No. **502092**.

### **3. Foreign Search Reports**

A copy of the PCT International Search Report from a counterpart application is enclosed. Legible copies of all items listed in Form PTO-1449 accompany this information statement. Cumulative patents or publications identified in the attached PCT Search Report are not enclosed.

I hereby certify that each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. 37 CFR 1.97 (e) (1).

The Applicant respectfully requests that:

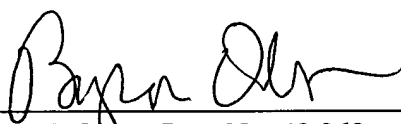
- a. The Examiner consider the cited information in reaching a determination concerning the patentability of the pending claims; and
- b. The enclosed Form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application.

The person making this statement is the attorney who signs below on the basis of the information in the attorney's file.

Dated: \_\_\_\_\_

9/15/04

By: \_\_\_\_\_

  
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Substitute for form 1449/PTO

SEP 17 2004

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

**(Use as many sheets as necessary)**

**Complete if Known**

Application Number	10/635,117
Filing Date	08/06/2003
First Named Inventor	Daniel E. Couto
Art Unit	1653
Examiner Name	Mondesi, Robert B
Attorney Docket Number	GTC-207

Sheet 1

of 3

Attorney Docket Number

GTC-207

## U. S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

**Examiner  
Signature**

Date \_\_\_\_\_

**Considered**

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Sheet	2	of	3	Application Number	10/635,117
				Filing Date	08/06/2003
				First Named Inventor	Daniel E. Couto
				Art Unit	1653
				Examiner Name	Mondesi, Robert
				Attorney Docket Number	GTC-207

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Andersson, "The Heterogeneity of Bovine Serum Albumin," BIOCHIM. BIOPHYS. ACTA. 117:115-133 (1966)	
		Alun, J. et al., Activity Of Microbial Peptidases, Oxidases, And Esterases In Lake Waters Of Varying Trophic Status, CAN J MICROBIOL 39(8):795-803 (1993)	
		Aranha-Creado et al., Cumulative Viral Titer Reduction Demonstrated By Sequential Challenge Of A Tangential Flow Membrane Filtration System And A Direct Flow Pleated Filter Cartridge, PDA J PHARM SCI TECHNOL 51 (5): 208-212 (1997)	
		Aravindan GR, et al., Identification, Isolation, And Characterization Of A 41-Kilodalton Protein From Rat Germ Cell-Conditioned Medium Exhibiting Concentration-Dependent Dual Biological Activities, ENDOCRINOLOGY, 138(8): 3259-68 (1997)	
		Federspiel G, et al., Hybridoma Antibody Production In Vitro In Type II Serum-Free Medium Using Nutridoma-SP Supplements: Comparisons With In Vivo Methods, J IMMUNOL METHODS 145(102): 213-221 (1991)	
		Gabler et al., Principles of Tangential Flow Filtration: Applications to Biological Processing, in FILTRATION IN THE PHARMACEUTICAL INDUSTRY, pp. 453-490 (1987)	
		Kahn DW, et al., Purification Of Plasmid DNA By Tangential Flow Filtration, BIOTECHNOL BIOENG. 69(1):101-106 (2000)	
		Kawahara H, et al., High-Density Culture Of FM-3A Cells Using A Bioreactor With An External Tangential-Flow Filtration Device, CYTOTECHNOLOGY 14(1):61-66 (1994)	
		Porter, ed., HANDBOOK OF INDUSTRIAL MEMBRANE TECHNOLOGY, (Noyes Publications, Park Ridge, New Jersey, 1990) pp. 160-176	
		Prado SM, et al., Development And Validation Study For The Chromatographic Purification Process For Tetanus Anatoxin On Sephacryl S-200 High Resolution, BOLL CHIM FARM, 138(7):364-368 (1999)	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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